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APPLICATION NO	F	ILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10 051,020	10 051,020 01.22.2002		Jonathan D. Oliner	03848.00100	9805
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BANNER & WITCOFF LTD.,				EXAMINER	
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ELEVENTH FLOOR WASHINGTON, DC 20001-4597				ART UNIT	PAPER NUMBER
				1635	
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Please find below and/or attached an Office communication concerning this application or proceeding.

## Application No. Applicant(s) OLINER ET AL. 10/051.020 Office Action Summary Examiner Art Unit Janet L. Epps-Ford, Ph.D. 1635 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1 136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U S C § 133) - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1 704(b) **Status** 1)[•] Responsive to communication(s) filed on 22 January 2002. 2a) This action is **FINAL**. 2b) This action is non-final. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 1 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. **Application Papers** 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). 11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action. 12) The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. §§ 119 and 120 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f) a) All b) Some \* c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). s 🦳 The strategical concentrate, the proposed conservation of a constraint continue to an including the proposed one had contact ್ತು Notice of References ulted P1ರ ಕಟ್ಟ Interview Summary, PTO 413, Paper No.s. 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Notice of Informal Patent Application (PTO-152) 3) N Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 40 80 6 4

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#### **DETAILED ACTION**

#### Specification

- 1. The numbering for the drawings found in the Brief Description Of The Drawings is objected to because the text at p. 5, recites "Figures 2A through 2F" and "Figures 3A through 3C", whereas the Figures 2 and 3, themselves, depict lower case "a" through "f" and lower case "a" through "c", respectively. Correction is necessary.
- 2. The disclosure is objected to because of the following informalities: Some of the text of the specification as filed is either missing or blurred, and therefore illegible. See for example the text located on page 1, lines 16-17, pages 2-42, lines 25-26, and page 43-45, lines 20-21.

Appropriate correction is required.

#### Claim Rejections - 35 U.S.C. § 112

- 3. The following is a quotation of the second paragraph of 35 U.S.C. 112:
  - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 4. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- Claim 1 recites the limitation "the set" in line 16. The metes and bounds of this limitation are vague and indefinite since it is unclear which set of genes "the set" refers to. Claim 1 uses the terminology "a set of genes" to refer to "a set of genes in the two

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meanings. The claimed method lacks clarity since the ordinary skilled artisan would not be able to reasonably ascertain which set of genes Applicants are referring to in regards to "the set" as recited in the last step of the claimed method.

### **Double Patenting**

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fcd. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,340,565. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentably distinct

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method of determining candidate functional mediators of a selected gene," wherein said method comprises the steps of altering the expression of a gene, comparing expression levels of a set of genes, identifying, altering, comparing and finally identifying genes that are candidate functional mediators of a selected gene. However, instant claim 1 differs in scope with issued claim 1, for example, the method of instant claim 1 (line 16) comprises, in step (f), identifying genes in "the set," wherein "the set" may read on "a set of genes" in two populations of cells in step (b), or "a set of genes" in a third and fourth population of cells in step (c). However, the last step of the method recited in issued claim 1 (step f) is limited to identifying genes in "the second set of genes" which clearly correspond to "a second set of genes" as recited in step (e) of the method recited in issued claim 1. Instant claim 1 does not clearly set forth this distinction so that there is no ambiguity in regards to which set of genes Applicants are identifying in the final step of the claimed method. Therefore, claim 1 of U.S. Patent No. 6,340,565 falls entirely within the scope of instant claim 1 or, in other words, instant claim 1 is anticipated by claim 1 of U.S. Patent No. 6,340,565.

#### Remarks

7. It is noted that during the prosecution of the parent application 09/431,964, now issued US Patent No. 6,340,565, claim 1 was amended to clearly set forth which set of genes "the set" (in line 16 of claim 1) is referencing. If Applicants were to correct instant claim 1 in the same manner as issued claim 1 of US Patent No. 6,340,565 was amended, that amendment to instant claim 1 would potentially raise a new ground of rejection

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 703-308-8883. The examiner can normally be reached on M-T, Thurs-Fri, 8:30AM-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

ict L. Epps-Fold Str.D.

JLE June 13, 2003